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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,422	12/27/2005	Tina Rademacher	RO4126US (#90568)	3869

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,422	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-6,8-11,13 - 36* is/are pending in the application.

4a) Of the above claim(s) *15-19,30-32 and 36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,8-11,13,14,20-29 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments, filed January 10, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 4 – 6, 8 – 11, 13, 14, 21 – 29 and 33 – 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. (US 4,572,832) in view of Rault et al. (US 5,900,247). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 30, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Kigasawa et al. does not disclose a multi-layered dosage form utilizing a matrix-forming polymer from the Markush group of claim 1.

This argument is unpersuasive. A multi-layered dosage form is taught by Rault and Applicants do not present any specific arguments as to why this combination of references was improper as the response only recites what the Examiner set forth in the previous Office Action. Col 4, ln 39 of Kigasawa et al. discloses alginic acid, one of matrix forming polymers recited in amended claim 1, as a polyhydric alcohol contemplated for use in the composition. Alginic acid is listed in the Markush group of amended claim 1.

6. Claims 1, 4 – 6, 8 – 11, 13, 14, 21 – 29 and 33 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kigasawa et al. and Rault et al. as applied to

claims 1, 4 – 6, 8 – 11, 13, 14, 20 – 29 and 33 – 35 above, and further in view of Lydzinski et al. (US 2003/0099691).

As discussed in previous Office Actions in greater detail and above, Kigasawa et al. discloses soft buccal compositions which comprise a medicament to be absorbed through the oral cavity, a water-soluble protein, a polyhydric alcohol such as alginic acid and a fatty acid ester and/or a carboxyvinyl polymer (col 1, ln 36 – 49). Kigasawa et al. discloses that additives can be added in addition to the required ingredients, including flavorings (aroma substances) such as menthol, lemon oil and citrus flavor as well as other excipients, disintegrating adjusting agents, emulsifiers, dispersants, binders and thickeners (col 5, ln 56 – col 6, ln 6).

Kigasawa et al. does not explicitly disclose a formulation wherein the active substance is one or more aroma substances without a pharmaceutical active substance being included in the administration form.

Lydzinski et al. discloses an oral film that useful for delivering an agent to an animal or human to produce either a therapeutic or cosmetic effect, such as breath fresheners or fragrances (¶ [0006]), both of which read on the aroma substance of the instant claims. The active agent can be used in any amount desired, the only limitation being the potential load of the film, but generally, the amounts used will range from about 0.5% to about 15%, with substantially higher amounts for breath fresheners than for pharmaceutical agents (¶ [0024]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate an aroma substance in place of the pharmaceutically

active ingredient in the compositions of Kigasawa et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the inclusion of an aroma substance (breath freshener or fragrance) results in an oral film that quickly disintegrates in the mouth, leaving the user with fresh or scented breath.

The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. As Lydzinski et al. teaches, almost any amount of active substance can be present in the film and the type of active ingredient will determine how much is added, with pharmaceutically active substances generally being present in lower amounts than breath freshener ingredients, sp one would determine the optimal amount to add based on the particular active ingredient that is used and desired effect.

7. Claims 1, 4, 5, 9 – 11, 13, 14, 21, 22, 24, 25, 27 – 29, 33 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. (US 4,764,378) in view of Rault et al. (US 5,900,247). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 30, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Keith et al. does not disclose a multi-layered dosage form utilizing a matrix-forming polymer from the Markush group of claim 1.

This argument is unpersuasive. A multi-layered dosage form is taught by Rault and Applicants do not present any specific arguments as to why this combination of references was improper as the response only recites what the Examiner set forth in the previous Office Action. Col 4, ln 2 of Keith et al. discloses sodium alginate, an alginate, which is one of matrix forming polymers recited in amended claim 1, as a high molecular weight polymer contemplated for use in the composition.

8. Claims 1, 4, 5, 8 – 11, 13, 14, 21, 22, 24, 25, 27 – 29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieth et al. and Rault et al. as applied to claims 1, 4, 5, 9 – 11, 13, 14, 21, 22, 24, 25, 27 – 29, 33 and 34 above, and further in view of Bergeron (WO 99/53897) and Gibson (EP 0386960).

As discussed in greater detail in previous Office Actions and above, Keith et al. discloses buccal dosage forms containing up to 10% by weight active ingredient in a matrix-forming polymer mass such as alginate.

Keith et al. does not disclose the presence of an agent that alters the pH from the Markush group of claim 8.

Bergeron et al. discloses a formulation of film-forming ingredient and an active agent for topical formulations (p 1, ln 8 – 9). The pH of the formulation can be adjusted

to meet the requirements of the target tissue (p 13, ln 31 – 33). For formulations applied to the vaginal mucosa, a pH of about 4.0 – 4.5 should be used (p 13, ln 33 – 34).

Bergeron et al. does not disclose any agents that would adjust the pH depending on the target tissue.

Gibson et al. discloses that the pH of the compositions can be adjusted through the use of pharmaceutically acceptable acids or bases such as sodium or hydrochloric acid and that pH can be maintained by the use of buffering agents (p 9, ln 34 – 43).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a pH adjusting agent in the compositions of Keith et al. The person of ordinary skill in the art would have been motivated to make those modifications, and reasonably would have expected success because Bergeron et al. discloses that the pH of the formulations should be adjusted to meet the requirements of the target tissue and Gibson et al. discloses that one way to adjust the pH is through the use of compounds such as buffers, sodium hydroxide and/or hydrochloric acid. Determining the appropriate pH based on the intended use of the compositions and using acids, bases and/or buffers to provide a composition with that particular pH is within the skill of one of ordinary skill in the art.

9. Claims 1, 4 - 6, 9 – 11, 13, 14, 21 – 25, 27 – 29 and 33 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith et al. and Rault et al. as applied to claims 1, 4, 5, 9 – 11, 13, 14, 21, 22, 24, 25, 27 – 29, 33 and 34 above, and further in view of Lydzinski et al. (US 2003/0099691).

As discussed in greater detail above and in previous Office Actions, Keith et al. discloses buccal dosage forms containing up to 10% by weight active ingredient, in a matrix-forming polymer mass such as alginate. The active ingredients are pharmaceutically active compounds like scopolamine or verapamil hydrochloride.

Keith et al. does not disclose a formulation wherein the active substance is one or more aroma substances without a pharmaceutical active substance being included in the administration form.

Lydzinski et al. discloses am oral film that useful for delivering an agent to an animal or human to produce either a therapeutic or cosmetic effect, such as breath fresheners or fragrances (¶ [0006]), both of which read on the aroma substance of the instant claims. The active agent can be used in any amount desires, the only limitation being the potential load of the film, but generally, the amounts used will range from about 0.5% to about 15%, with substantially higher amounts for breath fresheners than for pharmaceutical agents (¶ [0024]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate an aroma substance in place of the pharmaceutically active ingredient in the compositions of Keith et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because the inclusion of an aroma substance (breathe freshener or fragrance) results in an oral film that quickly disintegrates in the mouth, leaving the user with fresh or scented breath. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would

routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. As Lydzinski et al. teaches, almost any amount of active substance can be present in the film and the type of active ingredient will determine how much is added, with pharmaceutically active substances generally being present in lower amounts than breath freshener ingredients, so one would determine the optimal amount to add based on the particular active ingredient that is used and the desired effect.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

NMW